Title: METHOD AND APPARATUS FOR CELL AND ELECTRICAL THERAPY OF LIVING TISSUE

REMARKS

This responds to the Office Action dated October 9, 2008.

Claims 1, 9-10, and 34 are amended, and claims 38-39 are added; as a result, claims 1-11, 13-34, and 37-39 are now pending in this application.

§103 Rejection of the Claims Using Chachques and Heynen

Claims 1-3, 6-10, and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chachques (U.S. Pub. No. 2002/0124855, herein "Chachques") in view of Heynen et al. (U.S. Patent No. 6,507,756, herein "Heynen").

Claim 1

Claim 1 has been amended. Support for the amendment is found, for example, one page 15, lines 8-18 of the present application as originally filed.

Applicant respectfully traverses the rejection and submits that Chachques and Heynen, individually or in combination with each other and reasoning given in the Office Action, do not provide the claimed subject matter. For example, Applicant is unable to find in Chachques and Heynen, individually or in combination, among other things, a pulse generator programmed to include a selectable pacing mode adapted to enhance the cell therapy, the selectable pacing mode adapted to provide therapeutic electrical stimulation which includes progressively loading or unloading a cardiac region over a predetermined time by dynamically and incrementally adjusting an atrioventricular delay by a predetermined amount on a predetermined periodic basis over the predetermined time, as recited in claim 1. Applicant is also unable to find a reason in the Office Action that addresses this deficiency of the cited references.

The Office Action asserts that "the 'predetermined amount' that the Av delay could be adjusted could be 'zero'." However, such an adjustment is believed not to provide a therapeutic electrical stimulation by progressively loading or unloading the cardiac region over a predetermined time, as recited in claim 1.

The Office Action also asserts that "[t]he phrase 'predetermined amount' is broad enough to encompass any adjustment, however slight, that the pacemaker would make under normal

circumstances." It is respectfully noted that claim 1 recites a pulse generator programmed to include a selectable pacing mode, rather than a pulse generator merely programmable according to the selectable pacing mode. In addition to the "predetermined amount", claim 1 also recites dynamically and incrementally adjusting the atrioventricular delay on a predetermined periodic basis over the predetermined time, which is believed not to encompass any adjustment that a pacemaker would make under "normal circumstances".

Applicant respectfully requests reconsideration and allowance of claim 1.

Claims 2-3 and 6-10

Applicant respectfully traverses the rejection. Claims 2-3 and 6-10 are dependent on claim 1, which is believed to be allowable for at least the reasons set forth above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 2-3 and 6-10.

Applicant respectfully requests reconsideration and allowance of claims 2-3 and 6-10.

Claim 34

Claim 34 has been amended to be an independent claim with additional limitations. Support for the amendment is found, for example, on page 14, line 28 to page 15, line 7 of the present application as originally filed.

Applicant respectfully notes that as amended, claim 34 includes limitations similar to those of claim 11, which has been allowed.

Applicant respectfully requests reconsideration and allowance of claim 34.

\$103 Rejection of the Claims Using Chachques, Heynen, and Bonnet

Claims 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chachques in view of Heynen and further in view of Bonnet (U.S. Patent No. 6,574,507, herein "Bonnet").

Applicant respectfully traverses the rejection. Claims 4 and 5 are dependent on claim 1, which is believed to be allowable for at least the reasons set forth above. It is believed that the addition of Bonnet does not remedy the deficiency of Chachques and Heynen as discussed for

Dkt: 279.466US1

claim 1 above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 4 and 5.

Applicant respectfully requests reconsideration and allowance of claims 4 and 5.

§103 Rejection of the Claims Using Chachques and Bornzin

Claims 1-3, 6-10, and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chachques in view of Bornzin (U.S. Patent No. 6,832,112, herein "Bornzin").

Claim 1

Claim 1 has been amended. Support for the amendment is found, for example, one page 15, lines 8-18 of the present application as originally filed.

Applicant respectfully traverses the rejection and submits that Chachques and Bornzin, individually or in combination with each other and reasoning given in the Office Action, do not provide the claimed subject matter. For example, Applicant is unable to find in Chachques and Bornzin, individually or in combination, among other things, a pulse generator programmed to include a selectable pacing mode adapted to enhance the cell therapy, the selectable pacing mode adapted to provide therapeutic electrical stimulation which includes progressively loading or unloading a cardiac region over a predetermined time by dynamically and incrementally adjusting an atrioventricular delay by a predetermined amount on a predetermined periodic basis over the predetermined time, as recited in claim 1. Applicant is also unable to find a reason in the Office Action that addresses this deficiency of the cited references.

The Office Action asserts that "Bornzin teaches the ability to adjust the AV delay when needed, by a programmable amount over a predetermined period of time." It is respectfully noted that claim 1 recites a pulse generator programmed to include a selectable pacing mode, rather than a pulse generator with a mere ability to be programmed according to the selectable pacing mode. Additionally, Bornzin relates to adjusting AV delay "to cause fusion of the externally provided ventricular pacing stimuli with the patient's own natural conducted cardiac rhythm" (column 3, lines 28-31), and discusses that the AV delay is shortened repeatedly "until the current AV/PV delay is at the shortest allowed interval" (column 13, lines 31-34). This

Filing Date: November 25, 2003

Title: METHOD AND APPARATUS FOR CELL AND ELECTRICAL THERAPY OF LIVING TISSUE

Dkt: 279.466US1

appears to teach away from adjusting the AV delay over a predetermined period of time as recited in claim 1.

The Office Action further asserts that "[t]o use such a feature with the device of Chachques would have been obvious since such would merely be a combination of known prior art elements yielding a predictable result." Applicant respectfully traverses this assertion as an improper conclusory statement without a properly articulated reason for the combination of Chachques and Bornzin. Chachques relates to "using a combination of cellular cardiomyoplasty and electrostimulation to synchronize the contractions of the transplanted cells with the cardiac cells. Applicant is unable to find a reason in the cited references and the Office Action why one of ordinary skill in the art would modify Chachques' device to include Bornzin's AV delay adjustment (for fusion of pacing stimuli with the patient's own natural rhythm). It is also unclear what the alleged "predictable result" is and why it is predictable.

Applicant respectfully requests reconsideration and allowance of claim 1.

Claims 2-3 and 6-10

Applicant respectfully traverses the rejection. Claims 2-3 and 6-10 are dependent on claim 1, which is believed to be allowable for at least the reasons set forth above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 2-3 and 6-10.

Applicant respectfully requests reconsideration and allowance of claims 2-3 and 6-10.

Claim 34

Claim 34 has been amended to be an independent claim with additional limitations. Support for the amendment is found, for example, on page 14, line 28 to page 15, line 7 of the present application as originally filed.

Applicant respectfully notes that as amended, claim 34 includes limitations similar to those of claim 11, which has been allowed.

Applicant respectfully requests reconsideration and allowance of claim 34.

Serial Number: 10/723,258 Filing Date: November 25, 2003

Title: METHOD AND APPARATUS FOR CELL AND ELECTRICAL THERAPY OF LIVING TISSUE

§103 Rejection of the Claims Using Chachques and Bornzin

Claims 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chachques in view of Bornzin and further in view of Bonnet.

Applicant respectfully traverses the rejection. Claims 4 and 5 are dependent on claim 1, which is believed to be allowable for at least the reasons set forth above. It is believed that the addition of Bonnet does not remedy the deficiency of Chachques and Bornzin as discussed for claim 1 above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 4 and 5.

Applicant respectfully requests reconsideration and allowance of claims 4 and 5.

Allowable Subject Matter

Applicant acknowledges that claims 11, 13-24 and 37 are allowed.

New Claims

New claims 38-39 are added. Support for the new claims is found, for example, on page 14, lines 8-27 of the present application as originally filed. It is believed that the new claims are appropriate for consideration in the present application and that no new matter is added.

Applicant respectfully requests consideration and allowance of claims 38-39.

Serial Number: 10/723,258 Filing Date: November 25, 2003

Title: METHOD AND APPARATUS FOR CELL AND ELECTRICAL THERAPY OF LIVING TISSUE

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6965 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date January 8, 2009

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<u>CERTIFICATE UNDER 37 CFR 1.8</u>: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 8, 2009.

Name

Signature